Medicare Participating Heart Bypass Center Demonstration:

Data Collection Design

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INTRODUCTION

This report, the fourth in a series of deliverables to HCFA, follows submission of the site visit protocol, the demonstration evaluation design, and the development of an appropriateness model. It is the last of the pre-implementation reports scheduled for delivery to the Health Care Financing Administration (HCFA).

This **Data Collection Design** presents the rationale for the evaluation, the data elements required, and the procedures for collecting them. We begin by discussing several economic issues of interest to HCFA, including sources of volume increases at the demonstration sites and the relevant savings to the Medicare program (if any), and demonstration administrative costs anticipated at the four hospitals. Next, we discuss data collection related to the evaluation of appropriateness of CABG and PTCA. Finally, we discuss assessment of the hospitals' marketing activities in order to measure their varying levels of success at promoting the demonstration.

TABLE OF CONTENTS

I. SOURCES OF VOLUME INCREASES

A. Research Issues and Questions

One measure of the success of the HCFA Heart Bypass demonstration will be the increase in CABG surgery at the demo hospitals. But because CABG volume may increase due to growing propensity to perform the operation, we are also interested in measuring changes in CABG market shares among the demo sites. A successful demo site will be one that not only increases total CABG volume but also increases its market share--presumably in part by marketing its designation as a demo site.

B. CABG Volume Data Collection Protocol

To complete this task, the evaluator will need data on all Medicare discharges in DRGs 106, 107, and 108 for 3 years preceding the start of the demonstration and then monthly through June of 1994 when the demonstration is terminated. (DRG 108 is included because many CABGs that will be grouped under DRGs 106 or 107 during the demo were grouped in DRG 108 prior to 1991.) For the three years prior to June 1991, we will request HCFA/BDMS to provide us with a tape containing all of the Part A data from the MedPAR files for any Medicare discharge in DRG 106, 107, or 108. These claims will be linked to hospital provider numbers. Once we have defined market areas for each demo site (in collaboration with each site), we will aggregate the claims by hospital, by DRG, by year. We will then further sum all hospital totals within each demo market area, producing market area estimates by DRG. The residual will constitute all

CABGs done nationally outside the four demo market areas. Demo site totals by DRG will then be compared to market area and nonmarket, national totals to establish baseline demo site market shares.

Beginning on a monthly basis in June 1991, BDMS will provide DRG 106, 107, and 108 Part A inpatient claims (all data items) based on the National Claims History File (which, in turn, is based on the Common Working File). These data will be periodically aggregated to the demo site, demo market area, and national level by the evaluator to recalculate demo site market shares.

II. NET MEDICARE PROGRAM SAVINGS

A. Research Issues and Questions

The basic evaluation question in this area is what the Medicare program would have paid each demo site for DRGs 106 and 107 in lieu of the negotiated bundled inpatient payment. A critical corollary question is what the program saved considering volume shifts from nondemo to demo hospitals.

Three levels of analysis are proposed. The first concerns only the inpatient hospital and physician allowable payments associated with DRGs 106 and 107 relative to the global inpatient demo payment. The second compares the payment for all outpatient services associated with a CABG patient treated at the demo hospital prior to versus during the demonstration. Finally, the third extends the second payment comparison to allow for payment differences due to changes in the demo site's market share. This is based on a

comparison of average net inpatient CABG payments in local non-demo hospitals, weighted by the change in market shares. If other hospitals are less expensive, on average, relative to the demo site's negotiated rate and the demo hospital's share increases, this term will be positive, implying a diminution of program savings.

B. Medicare Savings Data Collection Protocol

The data for this analysis begin with the Part A claims used in the determination of volume shifts. None of the dollar figures on the claims are used, however; only the HIC IDs and hospital IDs, along with the DRG classifying information utilized. The first task are to determine what HCFA would have paid the demo and other local competing CABG hospitals in lieu of the demonstration. Once the market areas have been identified, all hospitals performing Medicare CABG surgery can be identified in each market area. Using these hospital IDs, we will request from HCFA's PPS Impact File each hospital's:

- annual standardized amounts per discharge;
- DRG 106 and 107 relative payment values;
- outlier parameters for estimating outlier payments;
- the IME percentage add-on per case;
- average pass-through amounts per case; and
- PPS update factors (implicitly included in the other payment elements).

These elements uniquely determine what the Part A inpatient outlay would have been in each local hospital without a demonstration. These elements change annually and would be requested from HCFA on an annual basis.

Once a CABG patient has been identified, all other Part A and Part B services associated with a CABG admission would be gathered from a second pass of the Medpar or National Claims history Files. For one year prior to June 1991, we will request BDMS to identify all patients (using HICs) with a discharge in DRG 106 or 107 from any hospital in each demo site's local market. Specific hospital IDs will be provided once market areas are determined. Then, for all HIC numbers in this group, all MADRS Part A and B claims will be pulled for each patient covering the full year (unless the Claims History File is retrospective over the June 1990-91 period, in which case its detail is preferred). These claims will provide allowable payments by type of service and location for patients discharged either from a demo or competing local hospital. Also note that these claims would include services obtained outside the geographic market area.

A similar process would be done retrospectively on an annual basis using the National Claims History File. All claims associated with CABG patient HIC numbers during the year would be pulled in a second pass at year's end. Truncated utilization data for patients discharged near the end of the year would be captured in next year's retrospective run, or a few months after the end of the demonstration's third year. All data on each claim would be retrieved for potential analysis. With both HIC and hospital IDs on each claim, payments can be aggregated by service category (e.g., SNF), by patient, by hospital.

III. MICRO-COSTING OF VOLUME INCREASES

A. Research Issues and Methods

Micro-costing of volume increases is designed to test the hypothesis that by attracting more CABG patients, participating hospitals can lower their cost per case and become more efficient and profitable. Micro-costing can also reveal other important changes in input costs, intensity, and productivity that affect the costliness of CABG surgery as well.

To answer the research question of the demonstration's volume effects on CABG costs, we seek estimates of the size economies in each site, i.e.,

$$(1) \qquad (w,q) = \frac{dc(w,q)/dq}{c(w,q)/q} = \frac{MC_q}{AC_q}$$

where (w,q) = an estimate of size economies as a function of input prices (w) and the level of output (q), $dc(w,q)/dq = MC_q$ = the marginal cost of an increase in quantity produced, and $c(w,q)/q = AC_q$ = the average cost of a CABG admission. If equation (1) is <1, then size economies exist and average costs per case fall with rising volumes. $\geq$ 1 implies constant or increasing costs with either no gain or actual losses associated with greater CABG volumes.

There are two general approaches to quantifying size economies. The first involves econometric estimates of the hospital cost function with hospital total costs as the dependent variable and total DRG 106 and 107 volume, as explanatory variables. This approach is unsatisfactory in this instance because of our goal of isolating the cost effects to just two DRGs. It is highly unlikely that unbiased coefficients can be obtained when using total hospital costs regressed against DRG 106 and 107 volumes, given all the other confounding factors that influence total costs over time.

The second approach relies on micro-costing and is the approach currently in use in all four of the demonstration hospitals. This accounting approach attempts to disaggregate costs into departments, then into procedures within departments, and finally into inputs needed to produce each procedure. Procedure costs can then be aggregated by CABG patient to derive CABG-specific cost estimates.

Our research strategy is to use the micro-cost data to estimate size economies based on equation (1). Let us begin with a couple of definitions:

$$(2) \quad c(w,q) = VC + FC$$

$$(3) \quad AC_q = c(w,q)/q = AVC_q + AFC_q$$

where

c(w,q) = total "accounting" costs for either DRG 106 or 107,

VC = variable costs, and

FC = fixed costs (excluding capital which is currently treated as a pass-through),

AC_q = average costs,

AVC_q = average variable costs, and

AFC_q = average fixed costs.

Equation (3), evaluated in the base period, immediately gives us the denominator of equation (1), assuming costs have been accurately assigned to patients in DRGs 106 and 107. The question of size economies devolves to an estimate of marginal, i.e., variable, costs:

(4) $MC = dc/dq = dVC/dq$

Deriving valid estimates of marginal costs within two distinct DRGs is complicated by four factors. First, DRG-specific volume changes may be correlated with input price inflation over time. Second, patients may increase (decrease) in severity over time. Third, hospitals may become more technically efficient in treating CABG patients. And fourth, changes in other volumes besides DRGs 106 and 107 can have spillover effects. These problems become more obvious if we decompose variable costs as

(5) $VC = (VC/INP)*(INP/PROC)*(PROC/q)*q$

where INP = inputs (e.g., nursing hours, exam gloves), and PROC = total procedures used in treating the q cases in DRG 106 or 107. If variable costs are simply compared at two points in time over which CABG volumes have changed, the changes could be due to changes in any or all of the three ratios. The first ratio reflects input prices, which we presume to be outside the hospital's control and certainly in no way influenced by any one hospital's growth in CABG volumes. The third ratio (PROC/q) reflects procedure intensity (e.g., x-rays or drugs per patient) and changing medical technologies and case mix. If treatment is becoming complex while volumes are increasing, say, because of operating on riskier patients, this will bias our estimate of the pure volume effect on costs upwards and the cost savings of greater volumes downwards. It is generally the second term, inputs per procedure, that is considered the pure volume effect on variable costs, holding technology and product mix constant.

The derivative of equation (5), or marginal costs, can be determined by evaluating the following expression at base period input prices and procedure intensities:

$$(6) \quad MC_t = AVC_o + \sum_j \sum_g (C_{go})^*(INP_{gj})^*(PROC_{jo}/q_o)^*q_o$$

where

AVC_o = average variable cost (for either DRG 106 or 107) in the base period (o),

C_{go} = unit cost of the g-th input in the base period,

INP_{gj} = the change in the g-th input used in the j-th procedure over the period,

$PROC_{jo}/q_o$ = average number of j procedures per case in the base period, and

q_o = the number of cases in DRG 106 or 107 in the base period.

Note that in order to derive unbiased estimates of marginal costs with respect to volume changes alone requires evaluating changes in inputs per procedure using base period input prices and procedure intensities.

The final determination of size economies simply requires substituting estimates from equation (6) and from equation (3), evaluated in the base period, into equation (1). Assuming substantial fixed costs, this ratio is predicted to be considerably less than 1.0. The ratio could be near or above 1.0 if average fixed costs per case are small relative to average variable costs or if variable costs per case are rising rapidly. The latter situation could occur in a high occupancy hospital.

B. Micro-Costing Data Collection Protocols: St. Joseph's-Atlanta and University Hospital

To quantify marginal and average costs for specific DRGs in the base and current periods requires substantial data. St. Joseph's in Atlanta and University Hospital in Boston use similar systems. For these two systems, the data itemized in Table 1 would be required. From the PROCEDURE COST PROFILE database, individual unit costs and resource quantities are available. We would need these data for all procedures ever provided to a CABG inpatient as of May 1991 and on a quarterly basis thereafter for three years. The May 1991 unit cost values would allow us to weight changing input usage per

procedure by base period input costs to control for inflation. The May 1991 resource quantities would provide base period estimates of resource usage per procedure, while quarterly updates in the quantities would measure changes in the input rates per procedure.

Procedure counts come from another file and need to be averaged by procedure over all Medicare and non-Medicare DRG 106 or 107 patients in the year before the demonstration started to derive baseline average intensity rates. Baseline procedure intensity rates would be used to derive average variable costs per patient in the base period as well as to weight changes in inputs per procedure in deriving average changes in marginal costs. On a quarterly basis, these counts will show the changing intensity of care within DRG 106 or 107.

Three other kinds of costs need to be reported. The first is total indirect variable cost per procedure code. These costs, while not directly assignable to a specific procedure, are assignable to volume changes more generally and need to be added to the direct variable costs and prorated to individual procedures.

Next are two kinds of fixed costs, direct, ancillary department related, and indirect, general overhead. It is our understanding that these are allocated to procedures based on procedure counts. Fixed ratios are presumably available (or can be calculated) on a procedure basis. We would need these ratios as of May 1991 for estimates of average fixed costs in the base period per procedure. Quarterly updates, if these figures change, would allow us to calculate an average total fixed cost per CABG patient during and at the end of the demonstration.

In addition to these procedure or department averages, we will also require the following set of individual patient information from the general patient file:

- Patient Number (to link other medical record data)
- Medical Record No. (if different than patient no.)
- Sex
- Age
- Zip Code
- Cost Per Case
- Net Revenue Per Case
- Net Income Per Case
- Units Per Case
- Charge Per Case
- Length of Stay
- Operating Costs
- Variable Cost
- Fixed Cost
- Admission Date
- Discharge Date
- Discharge Status
- DRG
- Payor
- Payor Name
- Cost Outlier Payment
- LOS Outlier Payment
- ICD9-CM Principal Diagnosis

C. Micro-costing Data Collection Protocols: St. Joseph's Ann Arbor and Ohio State University

St. Joseph's Hospital in Ann Arbor uses the COMPASS system for its micro-costing. This system in terms of costing detail is between the first generation systems that applied hospital-wide cost-to-charge ratios to individual patient bills and the HBO and Transition

Systems approaches that build up costs from industrial engineering standards, e.g., average personnel hours per aerobic culture. As applied in St. Joseph's-Ann Arbor, COMPASS estimates a patient's cost according to

$$TC_p = \sum_j \sum_s CH_{sd} * CH_{pjd}$$

where

TC_p = total cost for the p-th patient,

CCH_{sd} = a cost-to-charge ratio of the s-th cost type in department d; and

CH_{pjd} = actual charges billed to the p-th patient for the j-th procedure produced in department d.

Total costs are derived as the product of department-specific cost-to-charge ratios times patient charges for each procedure or service.

The Query Management Facility (QMF) in use at Ohio State University is very similar to COMPASS. The only difference is one of detail. The QMF currently is capable of producing only two department-level cost-to-charge ratios per procedure: direct and indirect. Indirect costs are stepped down to approximately 40 departments and cost-to-charge ratios generated a la Medicare.

Estimates of the ratio of marginal to average cost are less accurate in either system because input prices (e.g., hourly wages, syringe prices) are not immediately distinguished from input levels per procedure. Thus, a procedure's cost-to-charge ratio can rise over time because of, for example, wage inflation, which would bias marginal cost estimates upwards when comparing cases at two points in time. Hospital charges also rise over time,

which can also bias upwards estimates of procedure intensity (which are embedded in patient-specific charges for the j-th procedure).

Fortunately, the COMPASS and QMF systems also report total quantities of individual procedures used by each patient. Hence, it will be possible to use base period average procedure quantities per CABG patient so that procedure intensity can be held constant. Input price inflation remains a problem. At one extreme, we can ignore the problem by weighting base period procedure intensity by the change in the procedure's various cost-to-charge ratios, assuming that declines reflect less resource usage per procedure due to size economies. This change, unfortunately, may also be due to unequal rates of input and service price inflation. At the other extreme, we can also use base period cost-to-charge ratios, assuming constant variable costs per procedure. In this case, the marginal-average cost estimate devolves to a simple function of the ratio of fixed to variable costs. Table 2 summarizes our data requirements for

St. Joseph's (Ann Arbor) and Ohio State University.

In addition to these procedure or department averages, we will also require the following set of individual patient information from the general patient file:

- Patient Number (to link other medical record data)
- Medical Record No. (if different than patient no.)
- Sex
- Age
- Zip Code
- Cost Per Case
- Net Revenue Per Case
- Net Income Per Case
- Units Per Case
- Charge Per Case
- Length of Stay
- Operating Costs
- Variable Cost
- Fixed Cost
- Admission Date
- Discharge Date
- Discharge Status
- DRG
- Payor
- Payor Name
- Cost Outlier Payment
- LOS Outlier Payment
- ICD9-CM Principal Diagnosis

IV. DEMONSTRATION ADMINISTRATIVE COSTS

Demonstration hospitals will have incurred two types of administrative costs specific to the demonstration. The first involves the costs of submitting an initial application with detailed costing and institutional descriptive materials. The second involves the on-going management of the demonstration team including both hospital and physician staffs.

Two kinds of reporting forms, or protocols, have been designed for acquiring retrospective costs involved in the initial bid and for prospective management costs associated with participation. Form 1 divides the retrospective bid phase into five chronological time periods with columns for filling in the personnel involved and the days involved for each task. Phase I concerns the initial decision to submit an application. Phase II covers the production of the original bid and includes 10 subtasks. Phase III covers the time involved in extensive questions submitted to the 10 finalist sites. Phase IV covers preparation for face-to-face negotiations with HCFA while Phase V includes the final contract negotiations.

The lengthy time lag between the completion of these tasks and filling out this form by participants is unfortunate but unavoidable, given the long decision process. We seek best estimates of time spent by identified staff--generally in 1/2 day increments. These responses will be useful as a rough guide to HCFA in determining how much effort is necessary to complete various subtasks in the bidding process.

Forms 2A through 2E capture the on-going demonstration costs to each site in five areas: general administration; billing/accounting; marketing; quality assurance; and reporting of data for evaluation. The forms should reflect well-delineated tasks and personnel with a minimum of staff overlap across forms. The content of each task is defined at the bottom of each form. The forms are designed to be filled out at the end of each month by those responsible for the on-going demonstration functions.

It is important that participants remember that the hours (and nonlabor dollars) reported on these forms should be specific to the demonstration and exclude any other

regular hours devoted to, for example, billing and accounting. It is our expectation that the demonstration will require only marginal hours for most hospital and physician staffs, as they will continue to perform the same tasks as before. One or two staff, however, may be dedicated to the demonstration for significantly greater time.

Myra Jones, for example, may already be re-designing the micro-costing system for her hospital time that would not count toward as demonstration related. She may spend additional time, however, designing a data tape layout for the evaluation staff to analyze CABG costs in her hospital. She may also have a programmer devote front-end time writing the programs necessary to pull the data, as well as on-going time every quarter pulling the micro-cost data off the system and shipping a tape to HER in Waltham, Mass.

Any new staff hired part- or full-time for the demonstration should be included. Existing staff should also count time devoted to the demonstration even though no additional compensation is received, i.e., it is a simple reallocation of time or unpaid overtime.

V. APPROPRIATENESS AND OUTCOMES IN MEDICARE HEART BYPASS DEMONSTRATION CENTERS

The primary goal is to develop a uniform database in the demonstration sites that will permit the evaluation of the appropriateness and proximate and one-year outcomes of CABG procedures. A second goal is to examine the possible effect of financial incentives created by the Demonstration on possible substitution of CABG and PTCA

procedures for each other. This latter goal is particularly germane given the expansion of PTCA applications to more and more extensive coronary artery disease.

Appropriateness of CABG and PTCA will be evaluated using the Appropriateness Model we have developed by a consensus methodology that closely follows that pioneered by the RAND Corporation (see draft report dated May, 1991).

Commonly used outcome measures include traditional medical outcomes, functional status and quality of life, and patient satisfaction with the care process. The data collection protocols submitted with this report address data needs only for medical outcomes such as mortality, operative and post-operative complications, relief of angina, and the need for subsequent hospitalizations that are directly or indirectly related to the treatment of coronary artery disease.

Measures of functional status and patient satisfaction have been omitted from data collection protocols because they are not currently collected by the demonstration sites, and their collection would require significant additional data gathering efforts. We feel strongly, however, that these are important outcome measures and that serious consideration should be given to including them. This is especially true since the fundamental goal of the Demonstration is to save resources while preserving the quality of care. Medicare should be aware of any deleterious effects of "skimping" on perceived outcomes as well as on medical outcomes.

VI. DATA COLLECTION PROTOCOLS

Three draft data collection protocols are presented:

(1) Clinical Base On CABG Patients

(2) Outcomes 12 Months Following CABG Discharge

(3) Evaluation of Clinical Indications for PTCA

These protocols represent revisions of an earlier version that reflect comments received from the demonstration sites. Major changes include the deletion of sections aimed at measuring pre- and post-operative functional status and a reference to including a standard instrument to measure patient satisfaction.

In addition, post-operative follow-up has been limited to a single point in time: one-year post-operatively. Finally, individual data items have been modified or removed. The main thrust has been to simplify and reduce the effort of data collection.

Still needed are common definitions for key terms such as:

- unstable angina;
- elective, urgent, or emergent CABG surgery; and
- common intra-operative complications.

Also highly desirable would be a single form that would contain both the "coronary artery disease map" and information on bypassed or dilated coronary artery stenoses.

A final general issue relates to the formatting of data collection instruments. To the maximum extent possible, data items should be in the Yes/No or "check the box" format to facilitate both data collection and analysis. The current drafts aim in this

direction. When agreement has been reached on data items to be collected and on definitions, we will prepare "user-friendly" instruments.

A. Clinical Database On CABG Patients

This instrument assesses:

- patient demographics;
- information on key dates with respect to the CABG procedure and physicians involved;
- clinical history including presenting symptoms, prior history of MIs and congestive heart failure, cardiac medications, prior cardiovascular procedures, critical co-morbid conditions, and risk factors;
- limited information from the physical examination;
- cardiac catheterization data;
- pre-operative non-invasive data that affect the risk of the procedure;
- pre-operative risk assessment;
- information on the operative procedure including intra-operative complications;
- post-operative complications; and
- discharge destination and medications.

Most of this information should be available from the Cardiac Surgery Registry, which the demonstration sites maintain. A few items may have to be recovered from the medical record and added to the Registry.

B. Outcomes 12 Months Following CABG Discharge

With the elimination of functional status, only four outcome measures are assessed:

- mortality including cause of death;
- angina status;
- cardiac medications; and
- hospital readmissions.

The best single source of these data will be the patient's primary physician. A phone call would be the surest way to obtain a high response rate. In addition, Medicare's MADRS or Common Working File could be accessed to obtain information on hospital readmissions and cardiac procedures. The fact and date of death could also be obtained from Medicare data, but the cause could not unless it occurred during a hospitalization.

A one-month time interval for post-discharge monitoring was included in the initial draft protocol to permit evaluation of the early phase of recovery and also to coincide with the timing of the post-discharge visit to the cardiac surgeon. This data point was removed, however, because of one surgeon's concern that consistent data would be difficult to obtain.

C. Evaluation of Clinical Indications for PTCA

This instrument parallels that for CABG and collects data essential for examining the appropriateness of indications for PTCA in our Appropriateness Model. The instrument remains as part of the evaluation because of the importance of tracking the substitution of PTCA for CABG as one (unintended) effect of the Demonstration. An

explicit decision is needed on whether to retain or exclude this part of the evaluation. If it is retained, our plan would be to minimize the work load on any one site by examining a relatively small random sample of PTCAs per demonstration site per year (n = about 200). If retained, the budget would need to be adjusted accordingly.

VII. POTENTIAL ADDITIONAL MEASURES OF APPROPRIATENESS AND OUTCOMES

Consideration needs to be given to adding three components to the evaluation plan:

(1) assessment of functional status and quality of life;

(2) assessment of patient satisfaction; and

(3) validation of measurements of the degree of coronary artery stenosis.

We indicate here only a few selected issues and options. Implementation of these components would require agreement on uniform protocols and would probably require additional resources both for data collection and analysis.

A. Assessment of Functional Status

Technological progress with CABG surgery has greatly improved its safety and effectiveness and has permitted its application to an ever-increasing spectrum of older and sicker patients. As a result, operative mortality has become much less of an issue, and functional status and quality of life after surgery have become relatively more important.

At the same time, standardized instruments for measuring functional status have been developed and applied to patients with a broad array of medical problems. Hence, measurement of functional status is both important and reliable.

Measurement of functional status in the Demonstration would involve two dimensions: (1) assessment of general well-being using a patient-completed, standardized instrument such as The Index of Well-Being developed by John Ware and colleagues; and (2) assessment of cardiac specific measures such as the degree of exertion before angina and anxiety over the risk of sudden death. To provide a meaningful assessment of the benefits of surgery, these parameters need to be measured both before and after surgery (the pre-measure thereby serving as a within-person control).

Steps required to implement functional status measurement would involve the choice of instrument; a decision whether to collect the data by means of a mailed or telephone survey (collection during an office visit has been shown to lead to biased results); a decision on whether to measure functional status on a random sample or on all CABG recipients; and, finally, a decision on timing of administration (e.g., 1 week, 2 weeks, or 4 weeks before elective CABG, timing for patients undergoing urgent or emergent procedures, and whether 1 month, 6 months, or 12 months after surgery). Each timing selection will involve tradeoffs.

B. Assessment of Patient Satisfaction

A burgeoning literature on patient satisfaction increasingly relates to the patient's perceptions of the technical quality of provider, success of communication, and involvement

of the patient in clinical decision-making, as well as traditional measures of satisfaction with the amenities of the care setting. Knowledge on these issues will be important to Medicare as it confronts decisions on the extension of the Bypass Center designation to other providers.

Ideally patient satisfaction in the Demonstration should be done according to a common protocol using the same instrument at each site. A number of well-tested instruments are available including these developed by the Hospital Corporation of America, the Group Health Association of America, and Cleary and colleagues in Boston. The survey instrument would be given to the patient at the time of discharge or mailed within one week of discharge, with telephone or mailed follow-up to achieve higher response rates. Results would be used both by the hospital to improve services and in the evaluation. Samples of CABG patients could be surveyed, rather than all patients, to reduce workload. One sampling strategy would be to survey all patients discharged over a defined period of time (e.g. for a two week period every quarter). As of now, however, each site will use its own patient satisfaction survey instrument.

C. Validation of Measurements of Coronary Artery Stenoses

The degree of stenosis in an affected coronary artery is one of the key determinants of the need for CABG or PTCA and the benefits to be expected from the procedure. At the same time, techniques for measuring the degree of stenosis and their reliability vary widely. Some of the demonstration sites rely primarily on "eyeball" measurements, while others use more objective measures obtained with calipers or computerized edge

techniques. If comparisons among demonstration sites are to be valid, measurements of the extent of coronary artery disease and its severity in affected vessels need to be made by objective techniques.

Two possibilities suggest themselves. One possibility would be to obtain agreement from all sites that they would uniformly use caliper techniques. The second possibility would be to "validate" measures in samples of patients by having randomly selected angiograms independently and blindly read by cardiologists or radiologists in other sites. The first option is simpler, but compliance is anybody's guess. The second option is more difficult but would provide an objective comparison among sites. The effort required would be modest if samples were limited to 20-30 angiograms per site per year of the demonstration.

VIII. FINALIZATION OF THE DATA COLLECTION PROTOCOLS

Three key steps are involved. The first is to discuss the options discussed under Section III and to evaluate the appropriateness of PTCA with HCFA. Decisions are needed, and each could involve the need for additional resources both for data collection and analysis. The second is to circulate the revised data collection protocols to the sites to obtain further feedback and to resolve residual questions on definitions. The third is to put the data collection instruments into a user-friendly format.

IX. MARKETING

To measure the success of the sites in promoting the demonstration and increasing CABG volume, the hospitals' marketing activities will be monitored. The marketing analysis will trace the experiences of the sites over the course of the evaluation and review and evaluate the reasons behind their varying levels of success. The relationship between specific marketing strategies and changes in hospital patient bases also will be assessed.

A. Collection and Analysis of Marketing Data

Analysis of the marketing activities at the demo sites requires the development of two data bases: a referring physician data base and a patient data base (see Tables 3 and 4). The physician data base will be composed of the following data elements:

- name of physician
- identification number
- age
- specialty
- zip code of business address
- privileges at demo hospital (Y/N)
- other hospital privileges (names, if available)
- number of patients referred to demo site, by age
- number of bypasses received by each patient referred

Most of the physician data elements will be information gleaned from referring physician follow-up surveys. While the demo site and/or the patient may be able to provide the name of referring physicians and whether or not they have privileges at the demo hospital, most of the information will have to be provided by the physicians themselves. Therefore, we suggest that, initially, all referring physicians (as identified by each patient) be mailed a survey as a matter of course. Once a physician has returned a

completed survey, the information can be entered into the hospital's data base, and the entry can be updated as future patients indicate that they have been referred by that physician. We suggest that all physicians identified by patients be checked against the physician list to ensure that physicians are not sent more than one survey. This physician data base will be downloaded and forwarded to the contractor on a quarterly basis.

The information obtained from this physician data base will be used to trace changes in physician referral patterns over the course of the demonstration and to compare the levels of success obtained by each hospital in reaching current and potential referring physicians.

The patient data base will be composed of the following data elements:

- patient's social security number
- date of birth
- origin by zip code
- number of prior bypasses (if any)
- referring physician
- primary insurer
- coverage in addition to Medicare (if any)
- special services used
- results of patient satisfaction survey

Compared to the physician data elements, most patient data will be relatively easy to obtain. Some elements (such as social security number, date of birth, patient origin, number of bypasses, insurer) may be obtained from patient records, while others (such as referring physician and services used) may be obtained only through a follow-up of patients by the hospital. These data will be forwarded to the contractor on a quarterly basis.

Patient satisfaction will be evaluated using hospital satisfaction surveys. These surveys will be distributed by the demo sites to all patients. The surveys will differ from site to site, as each site has developed its own instrument. Survey information, then, will be used to assess patient satisfaction *within* each site throughout the course of the demonstration. Satisfaction *across* sites will not be measured due to lack of uniformity in the instruments used; however some conclusions regarding patient satisfaction will be assessed across sites, as each survey asks some of the same basic satisfaction questions. This information will be sent to the contractor on a quarterly basis as well.

In addition, we will collect from each site qualitative information about their marketing activities, such as:

- Patient services offered both before and after start-up of the demonstration
- The marketing budget for the demonstration as well as that used prior to the demonstration start-up
- A marketing plan (updated when adjustments are made during the demonstration)
- Promotional materials developed by the sites for the demonstration
- Newspaper and journal articles resulting from the demonstration

This information, combined with the quantitative information gleaned from the patient and physician data bases, will allow us to assess which marketing activities seem to be most effective in promoting the demonstration site.

Using the information submitted by the hospitals, we will develop a database from which we will trace changes in physician referral patterns, patient origin, patient satisfaction, and sources of payment over the course of the demonstration. In addition, we

will examine differences in patient origin and volume between the demo sites and other hospitals in their MSAs using MedPAR data. These data will be analyzed to determine if increases in volume at the demo sites can be attributed to the marketing efforts of the four hospitals.

B. Patient/Physician Follow-Up Survey

The data elements outlined above will allow us to analyze marketing activities, physician referral patterns, and patient and physician satisfaction within demo sites. To analyze these items across the sites, we will develop a patient/physician follow-up survey instrument. The survey will be used to conduct telephone interviews for Medicare CABG patients at each demonstration site. We will interview 40 patients from each demo site, selected randomly from the patient data base of each hospital. We will also interview 40 patients, identified from beneficiary records on the MedPAR file, who received CABGs at competing hospitals in the market areas. CABG patients that have been cared for at competing hospitals in the region will also be included in the study in order to assess outcomes of non-demonstration site patients versus demonstration site patients. Questions for this survey will be formulated based on the first year's data we receive from the demonstration sites. We anticipate, however, that among the questions asked will be ones that explore the following issues:

- **Price**. The survey will include a set of questions to determine whether price was an important factor in selecting the hospital. Components of price that might be important include deductibles, required copayments, and issues

related to balance billing. Regardless of these factors, the beneficiary may also be influenced by the fact that the total price is known in advance.

For beneficiaries not receiving care at the demonstration site, the survey will collect information on the total out-of-pocket costs to the beneficiary to make comparisons of price.

- **Role of referring physician.** The survey will ask the beneficiary a series of questions to determine what types of physicians influenced the decision to seek care at the hospital and how they influenced that decision. For example, a beneficiary may not have chosen a specific hospital, but may have been referred to a cardiothoracic surgeon who admits to only one hospital. Alternatively, the beneficiary could have selected a specialist based upon that physician's admitting privileges.

- **Income.** The survey will include questions related to income, availability of supplemental insurance, and other factors that might influence beneficiaries' price sensitivity.

- **Surgery circumstances.** The survey will collect information related to the circumstances under which the procedure was performed (e.g. were the circumstances urgent? was the beneficiary hospitalized when the decision for surgery was made? etc).

- **Hospital-related factors.** The survey will attempt to identify the importance of other hospital-related factors, e.g., the hospital's reputation, location, accessibility, availability of required services, etc. In addition, the survey will attempt to assess the importance of hospital marketing efforts.

- **Satisfaction.** The survey will collect information on the patients' satisfaction with the services received and their perceptions of the quality of care provided by both the hospital and the surgeon.

- **Functional Status.** The patient will provide answers to questions assessing the level of physical function achieved subsequent to surgery.

As a follow-up to the beneficiary survey, we will survey a subset of 20 physicians identified at each site to gather information about their role in the selection of the hospital for the beneficiary. We will ask the physicians what factors influenced their choice of

hospital, whether or not demonstration hospital marketing activities were important in their decision, and how price factors were considered in their recommendation. With regard to quality, we will query the referring physician concerning delays in hospitalization, pre-admission communication with the demonstration site, perceived quality of care delivered, post-discharge communication with the demo site, post-discharge gaps in care, and continuity of care after discharge.

C. Analysis of Survey Results

In the first phase of survey analysis, we will generate two types of descriptive tables. First, we will generate a series of descriptive tables comparing responses from beneficiaries selecting demonstration hospitals to beneficiaries selecting non-demonstration hospitals. These tables will include statistical analyses to identify areas of real difference between demonstration and non-demonstration beneficiary choice patterns. This analysis will be conducted using the data discussed above.

Next, we will construct tables comparing the four demo sites to identify differences across hospitals and geographic areas. Included in this analysis, will be other information on the market areas related to demonstration sites. For example, we will compare data across sites related to number of competing hospitals, urban area size, etc.

In the second phase of survey analysis, we will develop a probit equation that will quantify the probability of a beneficiary selecting a demonstration site based upon several factors. We expect that this probability will be influenced by: the net price of the services to the beneficiary (deductibles, copayments, and other out-of-pocket expenditures including

balance billing for physicians); beneficiary income and wealth; health status at the time of surgery decision; hospital distance; waiting time; awareness of hospital marketing efforts; referring physician specialty, and physician admitting privileges:

$$Pb(DEMO) = p(NP, W, HS, DIST, WAIT, AWARE, REFMD)$$

where:

Pb(DEMO)	=	the probability that a prospective CABG patient will select a demonstration site
NP	=	net out-of-pocket price for the inpatient Part A and B services facing the beneficiary
W	=	patient wealth
HS	=	patient health status
DIST	=	patient travel distance from the hospital
WAIT	=	number of days delay in receiving the operation
AWARE	=	patient awareness if price and quality differences between the demonstration hospital and other local competitors
REFMD	=	vector of characteristics of the referring physician that would affect choice

To estimate the model, beneficiary survey data will be pooled across all hospitals within the demo market sites. The dependent variable will equal one if the beneficiary chose a demo hospital; zero otherwise. Net price will be the sum of Part A and Part B inpatient bills that were paid out-of-pocket possibly zero in the demo hospital. Data for the other questions will be self-reported, with the exception of health status where we will have pre-admission data on many patients.

In addition to the variables listed in the predicting equation, we will include five market-area dummies to control for unmeasured site effects. If any of these dummy

coefficients are significant, this will suggest other, unmeasured factors affecting choice that are systematic to the site. In this case, we will include other market-area variables and discuss the findings with demo hospital administrators in an attempt to explain the difference.

TABLE 1

MICRO-COSTING DATA COLLECTION ITEMIZATION FOR ST. JOSEPH'S (ATLANTA) AND UNIVERSITY HOSPITAL

	TIME PERIOD	
	Base Period	Evaluation Period
1) Individual Unit Costs, by resource code including: a) supply purchase prices/unit b) hourly wage rates or WLU or RVUs	As of May 1991	End of each quarter after May 1991
2) Resource Quantities by resource code	As of May 1991	End of each quarter
3) Procedure Counts by Patient by Procedure Code	Averaged by procedure over all patients in either DRG106 or 107 between June 1990-May 1991	Quarterly per patient averages by procedure
4) Total Indirect Variable Cost per Procedure Code	As of May 1991	End of each quarter
5) Direct Fixed Costs per Procedure Code, separately for salary, nonsalary, capital	As of May 1991	End of quarter
6) Indirect Fixed Costs per Procedure Code, by salary, nonsalary, capital	As of May 1991	End of quarter

TABLE 2

MICRO-COSTING DATA COLLECTION ITEMIZATION FOR ST. JOSEPH'S (ANN ARBOR) AND OHIO STATE UNIVERSITY

ITEM	TIME PERIOD	
	Base Period	Evaluation Period
1) All cost center cost-to-charge ratios for: St. Joseph's (Ann Arbor) 9 cost types (i.e., 4 direct; 5 indirect) Ohio State University 2 cost types, direct and indirect.	As of May 1991	End of each quarter
2) Procedure (service) counts by patient by procedure code	Average by procedure over all patients in either DRG106 or 107 between June 1990-May 1991	Quarterly per patient averages within DRG106 or 107 by procedure
3) Total prices (Pr) for each procedure (service) consumed for each patient during stay	Averaged by procedure over all patients in DRG106 or 107 between June 1990-May 1991	Quarterly per patient averages within DRG106 or 107 by procedure

TABLE 3

REFERRING PHYSICIAN	AGE	SPECIALTY	OFFICE ZIP CODE	HOSPITAL PRIVILEGES (Y/N)	NUMBER OF PATIENTS REFERRED			# OF BYPASSES		
					<65	>65	TOTAL	0	1	2+

TABLE 4

PATIENT	SS#	DATE OF BIRTH	ZIP CODE	# OF BYPASSES	REFERRING MD	PRIMARY INSURER	MEDIGAP (Y/N)	SERVICES PROVIDED

FORM 1

ADMINISTRATIVE TIME IN PREPARING AND NEGOTIATING MEDICARE HEART BYPASS CENTER CONTRACT

STAFF (Person-hours)

TASK																NON-LABOR COSTS ($)
I. Submitting of Initial Application																
II. Preparation of Original Bid																
(1) Introduction and Organizational Background																
(2) Determining Staffing																
(3) Gathering CABG Volume and Outcome Data																
(4) Determining Package Price																
(5) Marketing and Incentive																
(6) Quality of Care and Medical Market																

FORM 1 (continued)

ADMINISTRATIVE TIME IN PREPARING AND NEGOTIATING MEDICARE HEART BYPASS CENTER CONTRACT

STAFF (Person-hours)

TASK																	NON-LABOR COSTS ($)
(7) Facilities/ Capacity and Utilization																	
(8) Arrangements with Medicare Contractors																	
(9) Expected Impacts																	
(10) Demonstration and Evaluation Potential																	
III. Responses to Questions																	
IV. Preparing for and Participating in face-to-face negotiations. (Baltimore)																	
V. Final Bids/ Contract																	

FORM 2A

ADMINISTRATIVE TIME IN MANAGING HEART BYPASS CENTER DEMONSTRATION PROJECT

STAFF (Person-hours)

TASK: GENERAL ADMINISTRATION*																	NON-LABOR COSTS ($)
Year:																	
January																	
February																	
March																	
April																	
May																	
June																	
July																	
August																	
September																	
October																	
November																	
December																	

*Includes the overall coordination of demonstration project tasks, including planning, problem solving, internal data analysis, impact assessment, coordinating physician referral systems, managerial consultants, efficiency consultants, patient liasons, and any other task not classified elsewhere but associated with the demonstration project.

FORM 2B

ADMINISTRATIVE TIME IN MANAGING HEART BYPASS CENTER DEMONSTRATION PROJECT

STAFF (Person-hours)

TASK: BILLING / ACCOUNTING*																NON-LABOR COSTS ($)
Year:																
January																
February																
March																
April																
May																
June																
July																
August																
September																
October																
November																
December																

*Includes hospital, physician, and intermediary billing costs and any other accounting costs associated with the demonstration project.

FORM 2C

ADMINISTRATIVE TIME IN MANAGING HEART BYPASS CENTER DEMONSTRATION PROJECT

S T A F F (Person-hours)

TASK: MARKETING*

Year:																NON-LABOR COSTS ($)
January																
February																
March																
April																
May																
June																
July																
August																
September																
October																
November																
December																

*Includes media relations, public relations, and advertising costs associated with the demonstration project.

FORM 2D

ADMINISTRATIVE TIME IN MANAGING HEART BYPASS CENTER DEMONSTRATION PROJECT

STAFF (Person-hours)

TASK: QUALITY ASSURANCE*																NON-LABOR COSTS ($)
Year:																
January																
February																
March																
April																
May																
June																
July																
August																
September																
October																
November																
December																

*Includes review and assessment of data and any other QA costs associated with the demonstration project.

FORM 2E

ADMINISTRATIVE TIME IN MANAGING HEART BYPASS CENTER DEMONSTRATION PROJECT

S T A F F (Person-hours)

TASK: REPORTING OF DATA FOR EVALUATION*																NON-LABOR COSTS ($)
Year:																
January																
February																
March																
April																
May																
June																
July																
August																
September																
October																
November																
December																

*Includes the reporting of cost, volume, quality, risk factor, and marketing data from hospital, physicians' offices, and long-term patient records.

CLINICAL DATABASE ON CABG PATIENTS

I. PATIENT DEMOGRAPHICS

Name

SSN

Home address: street, city, state, zip code

Telephone:

Birth date: month/day/year

Race: Caucasian, Black, Hispanic, Asian, Native American, other

Sex: male, female

Employment Status: (during the past 3 months): full-time, part-time, homemaker, retired, disabled, long-term sick leave, unemployed and looking for work, temporarily laid off

Insurer: Medicare only, Medicare plus Medicaid, Medicare plus Medi-Gap, other

II. CABG HOSPITALIZATION

Name of hospital:

Key Dates: admission date, date of coronary angiography, and date of PTCA (if applicable), date of CABG surgery, discharge date

Referring Physician: name, practice address, phone, specialty

Name of principal CABG surgeon:

III. CLINICAL HISTORY

A. Clinical Presentation for the Present Admission

- Asymptomatic CAD
- Stable angina: Y, N, DK. If yes, Canadian Heart Association Classification (I - IV).
- Unstable angina: Y, N, DK.
- Myocardial infarction: type (Q-wave, non-Q-wave)

B. Prior History of CAD

Most recent MI date (<7 days; 8-30 days; >30 days) and type (Q-wave, non-Q-wave, DK)

History of CHF and functional class

Cardiac medications at time of admission: ACE inhibitor/s, antiarrhythmic/s, anticoagulants; antiplatelet/s, beta blocker/s; digitalis, diuretic/s, vasodilator, other

C. Previous Cardiac Procedures

CABG: date(s)

PTCA: date(s)

Valve replacement or repair: valve(s) involved, date(s)

Valvulopasty: valve(s) involved, dates(s)

Other Cardiac Procedures: LVA, VSD, ASD, cardiac trauma, pacemaker, AICD, other

Other Vascular Procedures: aortic aneurysm, carotid endarterectomy, peripheral vascular, other

D. Comorbid Conditions

Previous stroke or TIA: Y, N, DK.

Peripheral vascular disease, including claudication, surgery or angioplasty for PVD: Y, N, DK.

COPD on medications: Y, N, DK.

Renal failure: Creatinine > 2.0 mg/dl: Y, N, DK.

On dialysis: Y, N, DK.

Malignancy: Y, N, DK. If yes, specify type of malignancy

E. Risk Factors:

Smoking history: never, stopped, current (pack-years)

Serum cholesterol > 240 mg/dl: Y, N, DK. If yes, current therapy

Diabetes: Y, N, DK. If yes, current therapy

Hypertension: Y, N, DK. If yes, current therapy

Family history of CAD or sudden death before age 55: Y, N, DK.

IV. PHYSICAL EXAMINATION (CLOSEST TO DATE OF CABG)

Height, weight, body mass index

Blood pressure: <80 systolic, >160 systolic

Arrhythmia: A-V block, PVCs (Lown class) VT, VF, SVT

Evidence of carotid disease by ultrasound or angiography: Y, N, DK.

V. CARDIAC CATHETERIZATION DATA

Date and hospital at which catheterization performed

Left ventricular ejection fraction; method by which performed (LV gram, radionuclide, estimated or calculated)

Coronary Artery Disease Anatomy (see Attachment A)

Method by which degree of stenosis estimated: calipers, edge technique, eyeball.

Complications:

Any or None; if Any check those that apply: cardiogenic shock requiring IABP or LVAD, cerebrovascular accident, TIA, MI, increase in angina requiring PTCA, local bleeding, other (specify)

VI. PRE-OPERATIVE NON-INVASIVE TEST DATA

ETT shows: > 1 mm, angina, SBP falls: Y, N. DK

Angina develops in stages I or II: Y, N, DK

SBP falls: Y, N, DK

Exercise or stress thallium shows redistribution: Y, N, DK

Exercise gated blood pool shows fall in EF or new wall motion abnormalities: Y, N, DK

VII. PRE-OPERATIVE CABG SURGERY RISK ASSESSMENT

Revascularization priority: elective, urgent (unscheduled and less than 24 hours after an acute event), emergent (unscheduled and less than 6 hours after an acute event)

Patient origin: ward, CCU, cath lab, other

Anginal status at time of surgery: stable, unstable, post AMI, other.

Pre-operative use of IABP

Pre-operative use of thrombolytic agents: agent and interval between use and CABG

VIII. OPERATIVE DATA

Primary Procedure: CABG, valve, other

Other Cardiac: LVA, VSD, ASD, pacemaker, AICD, angioplasty, endarterectomy, other

Other Non-Cardiac: aortic aneurysm, carotid endarterectomy, other

Primary anesthetic technique: opioid/narcotic, inhalation, combination

Type(s) of myocardial protection: intermittent cross-clamp, crystalloid cardioplegia, blood cardioplegia, continous perfusion/no cross clamp, retrograde perfusion, topical hypothermia

Intra-op insertion of IABP: N, Y; if Y, indication for IABP

Intra-op insertion of VAD: N, Y; if Y, LVAD, RVAD, BVAD, TAH

Pacing required: atrial or ventricular; temporary or permanent

Operative times: cross clamp time, perfusion time, skin-to-skin time, total anesthesia time

Coronary Bypass Data -- Attachment B

Intraoperative use of blood bank products: type and number of units/ cc including whole blood, rbc, FFP, Cryo, platelets

Shed blood used: Y, N, DK.

Intra-operative complications: Y, N; if Y, check those that are applicable (insert list of commonly occurring complications)

IX. POST-OPERATIVE CLINICAL COURSE

Condition of patient on leaving the OR: alive, dead

Post-bypass pharmacological or mechanical support: inotropic agents > 12 hours, new permanent pacemaker, LVAD, RVAD, IABP, ventilator >48 hours

Blood bank products used: Y, N; if Y, RBC, FFP, Cryo, Platelets

Post-operative complications:

Operative: Y, N; if Y: Re-op for bleeding, Rep-op for graft occlusion, Re-op for other cardiac, Re-op for other non-cardiac.

Perioerative MI (new Q-waves Y, N, DK.

Infection: Y, N; if Y: sternum-superficial, sternum-deep, leg, IABP site, septicemia.

Neurologic: Y, N; if Y: stroke-permanent, stroke-transient, coma.

Pulmonary: Y, N; if Y: ventilator greater than 2 days, pulmonary embolism, pneumonia.

Renal failure requiring dialysis: Y, N .

Vascular: Y, N; if Y: aortic dissection, iliac/femoral dissection, arterial emblous requiring treatment.

Other: Y, N; if Y: heart block (requiring permanent PM), cardiac arrest, anticoagulant complication, tamponade, GI complications, multi-system failure.

Mortality: Y, N; if Y: Date _____; Cause of Death - cardiac, infection, neurologic, pulmonary, renal, valvular, vascular, other.

X. STATUS AT TIME OF HOSPITAL DISCHARGE

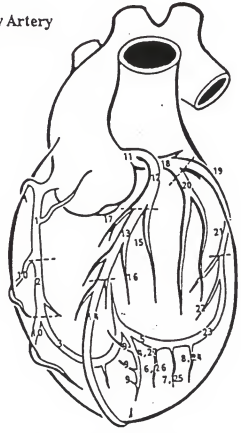
Medications at time of discharge (insert list)

Discharge Destination: home with family, home with home health care, rehabilitation facility, skilled nursing facility, other

ATTACHMENT A

CABG DATABASE - CORONARY ARTERY ANATOMY MAP

Right Coronary Artery
Seg. #
1. Prox RCA
2. Mid RCA
3. Dist RCA
4. RPDA
5. RPLS
6. 1st RPL
7. 2nd RPL
8. 3rd RPL
9. Inf. Septal
10. AC Marg.



Left Coronary Artery
Seg. #
11. LMCA
12. Prox LAD
13. Mid LAD
14. Dist LAD
15. 1st Diag
16. 2nd Diag
17. 1st Septal
18. Prox CX
19. Dist CX
20. 1st Ob Marg
21. 2nd Ob Marg
22. 3rd Ob Marg
23. LAV
24. 1st LPL
25. 2nd LPL
26. 3rd LPL
27. LPDA

From the illustration above, identify each lesion (up to 10 lesions) and insert the segment number and percent stenosis in the blank provided.

	1	2	3	4	5	6	7	8	9	10
Segment Number	____	____	____	____	____	____	____	____	____	____
% Stenosis	____	____	____	____	____	____	____	____	____	____

If there is a graft, insert segment number where graft is inserted (for up to five grafts).

Graft Segment Numbers _____ _____ _____ _____ _____

Collaterals Present ☐ Yes ☐ No

If yes, check all that apply:
☐ L-R
☐ R-L
☐ L-L

If Angioplasty or Atherectomy, Proceed to Blue Form.

ATTACHMENT B

CABG DATABASE - CORONARY BYPASSES PERFORMED

Coronary Bypass Data

Disease - Number of Vessels:

☐ Single
☐ Double
☐ Triple
☐ Left Main Disease

# of Dist Anast _____ # of Prox Anast _____

# of IMA Grafts _____ # of IMA Dist Anast _____

# of GEPA Grafts _____ # of GEPA Dist Anast _____

Endarterectomy Performed: ☐ No ☐ Yes

	% Stenosis	Distal Disease	Conduit	Endart ?	Prior PTCA ?
RM					
LAD					
D1					
D2					
Int Med					
Cx					
OM1					
OM2					
OM3					
PDA					
LVB					
AM					

Key for Table

% Stenosis
1 = 0 - 50 %
2 = 51 - 70 %
3 = 71 - 90 %
4 = 91 - 99 %
5 = 100 %

Distal Disease
1 = None
2 = Minimal
3 = Moderate
4 = Severe

Conduit
1 = SV
2 = LIMA
3 = RIMA
4 = Free-IMA
5 = GEPA
6 = Free GEPA
7 = Other

Endart ?
No/Yes

Prior PTCA ?
No/Yes

OUTCOMES 12 MONTHS FOLLOWING CABG DISCHARGE

I. **MORTALITY**

Date of death: month/day/year

Location of death: home, work, recreation, hospital, in transit to hospital, other

Cardiac symptoms prior to death: stable, worsening, improving, DK

Cause of death: cardiac, vascular but non-cardiac, other (specify)

Death related to a subsequent procedure: CABG, PTCA, cath, other. Describe circumstances

II. **HOSPITAL READMISSIONS**

(Record these data for all hospitalizations during the first year following CABG surgery)

Hospital name and location

Admission and discharge dates

Principal discharge diagnosis

Secondary discharge diagnoses

Procedures performed during the admission - cardiac and non-cardiac

III. **ANGINAL STATUS**

Patient is: hospitalized, ambulatory

(If patient is ambulatory, record anginal level during the preceding 2 weeks; if patient is hospitalized, record anginal level at the time of admission)

No angina

Stable angina and Canadian Cardiovascular Society Classification (I, II, III, IV)

Unstable angina

Pain c/w myocardial infarction

IV. **CARDIAC MEDICATIONS**

Cardiac currently prescribed: ACE inhibitor/s, antiarrhythmic/s, anticoagulants, antiplatelets, beta-blockers, calcium channel blockers, digitalis, diuretics, vasodilators, other (specify)_____.

EVALUATION OF CLINICAL INDICATIONS FOR PTCA

I. CLINICAL DATABASE FOR CABG

Name

SSN

Home address: street, city, state, zip code

Telephone:

Birth date: month/day/year

Race: Caucasian, Black, Hispanic, Asian, Native American, other

Sex: male, female

Employment Status: (during the past 3 months): full-time, part-time, homemaker, retired, disabled, long-term sick leave, unemployed and looking for work, temporarily laid off

Insurer: Medicare only, Medicare plus Medicaid, Medicare plus Medi-Gap, Other

II. HOSPITALIZATION FOR PTCA

Name of hospital

Date of PTCA

Referring physician: name, practice address, specialty

Name of principal invasive cardiologist

III. CLINICAL HISTORY

A. Clinical Presentation for the Present Admission

- Asymptomatic CAD
- Stable angina: Y, N, DK. If yes, Canadian Heart Association Classification (I - IV).
- Unstable angina: Y, N, DK.
- Myocardial infarction: type (Q-wave, non-Q-wave)

B. Prior history of CAD

Most recent MI: <2d; 3-7d; 8-30d; >30d date, type (Q-wave, non-Q-wave, DK)

History of CHF and functional class: Y, N, DK, NYHA Class-IV

Cardiac medications at time of admission: ACE inhibitor/s, antiarrhythmic/s, anticoagulants; antiplatelet/s, beta blocker/s; digitalis, diuretic/s, vasodilator, other

C. Previous Cardiac or Vascular Procedures

CABG: date(s)

PTCA: date(s)

Valve replacement or repair: valve(s) involved, date(s)

Valvulopasty: valve(s) involved, dates(s)

Other Cardiac Procedures: LVA, VSD, ASD, cardiac trauma, pacemaker, AICD, other

Other Vascular Procedures: aortic aneurysm, carotid endarterectomy, peripheral vascular, other

D. Comorbid Conditions

Previous stroke or TIA: Y, N, DK.

Peripheral vascular disease, including claudication, surgery or angioplasty for PVD: Y, N, DK.

COPD on medications: Y, N, DK.

Renal failure: Creatinine > 2.0 mg/dl: Y, N, DK.
On dialysis: Y, N, DK.

Malignancy: Y, N, DK. If yes, specify type of malignancy

E. Risk Factors:

Smoking history: never, stopped, current (pack years)

Serum cholesterol > 240 mg/dl: Y, N, DK. If yes, current therapy

Diabetes: Y, N, DK. If yes, current therapy

Hypertension: Y, N, DK. If yes, current therapy

Family history of CAD or sudden death before age 55: Y, N, DK.

IV. PHYSICAL EXAMINATION

Blood pressure: <80 systolic, >160 systolic

Arrythmia: NSR, PVCs (Lown class), AV block, VT, VF, SVT

Clinical signs of CHF: Y, N, DK.

V. CARDIAC CATHETERIZATION DATA

Date and hospital at which catheterization performed

Left ventricular ejection fraction; method by which performed (LV gram, radionuclide, estimated or calculated)

Valve disease: aortic, mitral, pulmonary, tricuspid; if stenosis provide gradient; if regurgitation, judge degree as mild, moderate, or severe

Coronary Artery Disease Anatomy - see Attachment A

Method by which degree of stenosis estimated: calipers, edge technique, eyeball.

Complications:

Y, N; if Y, check those that apply: cardiogenic shock requiring IABP or LVAD, cerebrovascular accident, TIA, MI, increase in angina requiring PTCA, local bleeding, other (specify)

VI. **PRE-OPERATIVE NON-INVASIVE TEST DATA** (DK implies test not obtained)

ETT shows: > 1 mm, angina, SBP falls: Y, N. DK

Angina develops in stages I or II: Y, N, DK

SBP falls: Y, N, DK

Exercise or stress thallium shows redistribution: Y, N, DK

Exercise gated blood pool shows fall in EF or new wall motion abnormalities: Y, N, DK

VII. **PRE-PTCA RISK ASSESSMENT**

Revascularization priority: elective, urgent, emergent

Patient origin: ER, ward, CCU, cath lab, other

Was this procedure a repeat PTCA for abrupt reclosure: Y, N, DK.

Anginal status at time of procedure: stable, unstable, post AMI, other

Pre-procedure use of thrombolytic agents: type of agent; interval between administration and PTCA

VIII. **PTCA PROCEDURE DATA**

Approach: Brachial, femoral

Number of intended lesions to be treated during this procedure:_____

Complete the attached Coronary Anatomy Map and indicate below the code numbers of "intended" lesions

Segment #s _____ _____ _____ _____ _____ _____

_____ _____ _____ _____ _____ _____

Was the change in vessel diameter from before to after the procedure less than 20% for any intended lesion? Y, N. If Y, indicate segment number(s) and reason(s) -- Attachment B

Was thrombolytic therapy given during the procedure: Y, N

Complications during the procedure: Y, N. If Y, check all that apply: MI, VF, other arrhythmia, TIA, hypotension requiring vasopressors, hypotension requring IABP, thrombolytic therapy for thrombosis, tamponade, emergency CABG

Condition of patient on leaving the lab: stable, unstable, dead

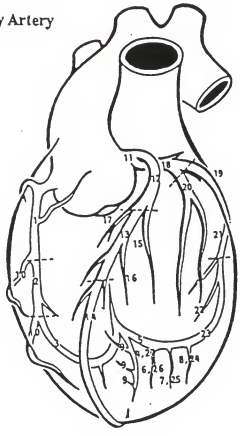
IX. POST-PTCA CLINICAL COURSE

Were any complications experienced following the procedure? Y, N, DK

If Y, check all that apply: -- Attachment C

PTCA DATABASE - CORONARY ARTERY ANATOMY MAP

Right Coronary Artery
Seg. #
1. Prox RCA
2. Mid RCA
3. Dist RCA
4. RPDA
5. RPLS
6. 1st RPL
7. 2nd RPL
8. 3rd RPL
9. Inf. Septal
10. AC Marg.



Left Coronary Artery
Seg. #
11. LMCA
12. Prox LAD
13. Mid LAD
14. Dist LAD
15. 1st Diag
16. 2nd Diag
17. 1st Septal
18. Prox CX
19. Dist CX
20. 1st Ob Marg
21. 2nd Ob Marg
22. 3rd Ob Marg
23. LAV
24. 1st LPL
25. 2nd LPL
26. 3rd LPL
27. LPDA

From the illustration above, identify each lesion (up to 10 lesions) and insert the segment number and percent stenosis in the blank provided.

	1	2	3	4	5	6	7	8	9	10
Segment Number	____	____	____	____	____	____	____	____	____	____
% Stenosis	____	____	____	____	____	____	____	____	____	____

If there is a graft, insert segment number where graft is inserted (for up to five grafts).

Graft Segment Numbers _____ _____ _____ _____ _____

Collaterals Present ☐ Yes ☐ No

If yes, check all that apply:
☐ L-R
☐ R-L
☐ L-L

If Angioplasty or Atherectomy, Proceed to Blue Form.

ATTACHMENT B

PTCA DATABASE - REASONS FOR INABILITY TO DILATE

Segment number code		___	___	___	___	___	___	___	___
Check primary reason for above (check only one)									
Inability to cross the lesion									
Inability to enter the artery	1	( )	( )	( )	( )	( )	( )	( )	( )
Inability to pass wire	2	( )	( )	( )	( )	( )	( )	( )	( )
Inability to pass balloon	3	( )	( )	( )	( )	( )	( )	( )	( )
Other cause, specify _____	4	( )	( )	( )	( )	( )	( )	( )	( )
Inability to dilate the lesion									
Complication	5	( )	( )	( )	( )	( )	( )	( )	( )
Rigidity of the lesion	6	( )	( )	( )	( )	( )	( )	( )	( )
Elasticity of the lesion	7	( )	( )	( )	( )	( )	( )	( )	( )
Technical failure	8	( )	( )	( )	( )	( )	( )	( )	( )
Other cause, specify _____	9	( )	( )	( )	( )	( )	( )	( )	( )
Did not attempt: Clinical Reason	10	( )	( )	( )	( )	( )	( )	( )	( )
Did not attempt: Technical	11	( )	( )	( )	( )	( )	( )	( )	( )

ATTACHMENT C

PTCA DATABASE - POST-PROCEDURE COMPLICATIONS

☐ Angina requiring therapy but not returned to lab.
☐ Returned to Lab _____# hrs. post procedure.
Thrombolytic therapy: ☐ Yes ☐ No
PTCA/Atherectomy: ☐ Yes ☐ No
Valvuloplasty: ☐ Yes ☐ No
Segment #____
If repeat PTCA/Atherectomy:
Same lesion: ☐ Yes ☐ No
Different lesion: ☐ Yes* ☐ No

*Note: (If different lesion, generate new form).

Result if same lesion:
☐ Success: Re-open to previous degree.
☐ Unsuccessful: Unable to Re-open.
☐ Partial Success: Re-open, but less than previous.

Disposition:
☐ CABG
☐ Further intervention: Specify _____
☐ Return to ward or CCU/ICU

☐ Major entry site complications:

- ☐ Vessel occlusion
- ☐ Large hematoma prolonging hospital stay
- ☐ Pseudoaneurysm
- ☐ Bleeding requiring transfusion
- ☐ Surgical repair required
- ☐ Cholesterol embolism
- ☐ Other: _____

☐ Cerebrovascular Accident
☐ MI:
☐ Time after procedure: ___hrs
Peak CPK ___ MB% ___ # hrs to peak ___
Q wave ___ Non-Q wave ___
☐ IABP
☐ Left Heart Assist Device

Hospital Death: ☐ Yes ☐ No Date:____/____/____

Location: In-Lab ☐ Yes ☐ No CCU/ICU ☐ Yes ☐ No
Post CV Surgery ☐ Yes ☐ No
Pre-Hosp Discharge ☐ Yes ☐ No

Cause: ☐ Cardiac ☐ Renal
☐ Infection ☐ Valvular
☐ Neurologic ☐ Vascular (other than cardiac)
☐ Pulmonary ☐ Other
(specify):_____